Express Mail Label No. EV342610567US

Dated: July 18, 2003

Docket No.: CIMA 3.0-036 CONT

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Pather, et al.

Application No.: Not Yet Assigned

Group Art Unit: N/A

Filed: Herewith

Examiner: Not Yet Assigned

For: SEQUENTIAL DRUG DELIVERY SYSTEMS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## **INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in Application No. 09/901,983, the benefit of which is claimed under § 120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account No. 12-1095.

Dated: July 18, 2003

Respectfully submitted,

Michael H. Teschner

Registration No.: 32,862

LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant

PTO/SB/08A (10-01)

Approved for use through 10/31/2002.OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Subs	titute for form 1449A/PT	0		Complete if Known		
				Application Number	To be assigned	
IN	<b>FORMATIC</b>	N DISC	CLOSURE	Filing Date	Herewith	
S	<b>TATEMENT</b>	BY AF	PLICANT	First Named Inventor	S. I. Pather	
				Art Unit	N/A	
	(use as many	sheets as ne	cessary)	Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	CIMA 3.0-036 CONT	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear		
	AA	4,756,710	07-12-1988	Bondi et al.			
	AB	5,624,687	04-29-1997	Yano et al.			
	AC	5,853,748	12-29-1998	New			
_	AD	5,900,252	05-04-1999	Calanchi et al.			
	AE	5,952,004	09-14-1999	Rudnic et al.			
	AF	6,034,085	03-07-2000	Joshi et al.			
	AG	6,068,853	05-30-2000	Giannos et al.			
***	AH	6,117,912	09-12-2000	DiSanto			
	Al	6,264,981 B1	07-24-2001	Zhang et al.			
	AJ	6,326,360 B1	12-04-2001	Kanazawa et al.			
	AK	6,326,384 B1	12-04-2001	Whittle et al.	-		

		FOREI	GN PATENT	DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁰
	BA	EP-0 197 504- A2	10-15-1986	Bondi et al.		T
	BB	EP-0 354 973- B1	02-21-1990	Paradissis	<u> </u>	T

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

Examiner	 	 • •	Date	
Signature			Considered	

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sub	ostitute for form 1449A/PTO	** ;		Complete if Known			
				Application Number	To be assigned		
11	<b>VFORMATION</b>	N DI	SCLOSURE	Filing Date	Herewith		
l s	STATEMENT I	BY /	APPLICANT	First Named Inventor	S. I. Pather		
				Art Unit	N/A		
	(use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned		
Sheet	2	of	2	Attorney Docket Number	CIMA 3.0-036 CONT		

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	RANADE, V.V.; Drug Delivery Systems Part 5B. Oral Drug Delivery, The Journal of Clinical Pharmacology, Feb. 1991, pp. 98-115, Vol. 31.	
	СВ	GIANNOS, S.A.; DINH, S.M.; BERNER, B.; Temporally Controlled Drug Delivery Systems: Coupling of pH Oscillators with Membrane Diffusion, Journal of Pharmaceutical Sciences, May 1995, pp. 539-543, Vol. 84, No. 5.	
	СС	AMIGHI, K.; TIMMERMANS, J.; PUIGDEVALL, J.; BALTES, E.; MOËS, A J.; Peroral Sustained-Release Film-Coated Pellets as a Means to Overcome Physicochemical and Biological Drug-Related Problems. I. In Vitro Development and Evaluation, Drug Development and Industrial Pharmacy, 1998, pp. 509-515, vol. 24, no. 6.	
	CD	SORASUCHART, W.; WARDROP, J.; AYERS, J.; Drug Release from Spray Layered and Coated Drug-Containing Beads: Effects of pH and Comparison of Different Dissolution Methods, Drug Development and Industrial Pharmacy, 1999, pp. 1093-1098, Vol. 25, No. 10.	
	CE	BERKO, S.; REGDON JUN, G.; ERÖS, I.; Influence of pH Change on Drug Release from Rectal Suppositories, Die Pharmazie, April 2000, p.324, Vol. 55., Govi-Verlag Pharmazeutischer Verlag GmbH, Eschborn.	
	CF	STREUBEL, A.; SIEPMANN, J.; DASHEVSKY, A.; BODMEIER, R.; pH-Independent Release of a Weakly Basic Drug from Water-Insoluble and -Soluble Matrix Tablets, Journal of Controlled Release, 2000, pp. 101-110, Vol. 67.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	<del> </del>	Date	
Signature	1	Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.